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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/500,135	02/08/2000	David A. Estell	A-68893/DJB/DAV	2164
5100	7590	04/19/2004	EXAMINER	
GENENCOR INTERNATIONAL, INC. ATTENTION: LEGAL DEPARTMENT 925 PAGE MILL ROAD PALO ALTO, CA 94304			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 04/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

500,135

Applicant(s)

ESTELL et al

Examiner

SAUNDERS

Group Art Unit

1644

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on 1/15/04
- ☒ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 2, 5, 7, 14, 29-34, 39, 41 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 2, 5, 7, 29-34, 41 is/are rejected.
- ☒ Claim(s) 14, 39 is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
 - ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
 - ☐ received in Application No. (Series Code/Serial Number) _____.
 - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other _____

Office Action Summary

Amendment of 1/15/04 has been entered.

Claims 2, 5, 7, 14, 29-34, 39 and 41 are pending and under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment has overcome the previously stated (action of 5/7/03) rejection under 35 USC 112, first paragraph.

Likewise, the amendment of claim 41 has overcome the 102 rejection over Estell (WO 99/53078).

The amendment necessitates the herein below stated prior art.

Claims 2, 5, 7 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Carr (WO 98/52976 of record in I.D.S. of 2/11/02) in light of Collen (5,951,980).

Carr shows modification of streptokinase by identifying T-cell epitopes therein and then modifying these epitopes by substitution of amino acid residues within these epitopes. See pages 4 and 35-38. With these modifications the streptokinase is less immunogenic. Claim 2 is thus anticipated.

Claim 5 is anticipated since streptokinase is not endogenous to humans (page 36, lines 17-19).

Claim 7 is anticipated since Carr substitutes amino acid residues--K for I and ^{for γ} F_A in each of the respective epitopes taught at page 37. Compare sequences in Figs. 28 and 29.

It is noted that Collen provides an extrinsic teaching (col.1, lines 58-67) that staphylokinase and streptokinase may induce anaphylaxis. This is a type of

Art Unit: 1644

allergic/hypersensitive reaction (see Herbert et al. definition). Thus the modified streptokinase of Carr inherently has a lowered allergenicity.

Claim 41 is presently included since Carr teaches (page 9, lines 8+) that modification of a T-cell epitope involves "alteration of one or more amino acids", this certainly encompasses "two amino acid residues" recited in claim 41.

Applicant's arguments filed 1/15/04 have been fully considered but they are not persuasive. Applicant's response has considered that deletion of "wherein said kinase is not a streptokinase" would open claim 2 to a restatement of the rejection over Carr. Applicant has urged that the streptokinase of Carr is not a "kinase" because it does not have any enzymatic activity of phosphorylating a protein.

This argument is unconvincing because instant claim 2 merely recites a "polypeptide of interest" with no requirement that this have any enzymatic activity. Since the streptokinase of Carr is a polypeptide it is considered to be properly encompassed by recitation of "kinase" in the claim, assuming the broadest reasonable interpretation of "kinase."

New grounds of rejection follow:

Regarding obviousness type double patenting issues, examiner notes that the claims of this application have previously been disclaimed over those of application 09/255,501, now pat. 6,596, 525 and 09/060,854, now pat. 6,642,011. Claims of the former pertain to proteases with reduced allergenicity; while claims of the latter pertain to methods of producing a protease with reduced allergenicity. The instant claims do

Art Unit: 1644

not encompass any protease; therefore a new obviousness type allowable patenting rejection is appropriate.

Claims 2, 5, 7, 29-34 and 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 7 of copending Application No. 09/768,080. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant and copending claims are drawn to common subject matter. Instantly the claims are limited to proteins with reduced allergenicity, wherein the proteins are limited to a Markush group of various well known classes of enzymes; the copending claims more broadly limit the proteins with reduced allergenicity to the subgenus of enzymes. The instant claims are thus drawn to a plurality of species of enzymes encompassed by the copending claims. A disclaimer is required to assure that the instant and copending claims, if both issued, would remain commonly assigned.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Carr et al (WO 00/34317) are cited as of interest.

Carr et al ('317) teach therapeutic proteins which have altered T-cell epitopes such that immunogenicity of the protein is reduced or eliminated.

Carr et al ('317) teach that the therapeutic proteins include staphylokinase streptokinase and phospholipase C (page 8, lines 1-5). They teach epitope alteration can be achieved by alteration of one or more amino acids ---e.g. by substitution (page 10, lines 23-30).

Art Unit: 1644

Applicant's amendment (of claim 41) necessitated the new ground(s) of rejection (double patenting) presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication from the examiner should be directed to David A Saunders, PhD whose telephone number is 571-272-0849.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571-272-0841.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Saunders/tgd

April 14, 2004

David A Saunders
DAVID SAUNDERS
PRIMARY EXAMINER
ART UNIT 182/644